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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,672	07/02/2004	Maria A. Bednarek	20954P	3103

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1656

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/500,672

Applicant(s)

BEDNAREK, MARIA A.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-38, 40 and 41 is/are rejected.
- 7) ☒ Claim(s) 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 29-41 are pending.

Applicant's response filed December 8, 2006 is acknowledged and has been fully considered. Claims 1-21, 23 and 25-28 have been cancelled, and new claims 29-41 have been added. Therefore, claims 29-41 are examined.

Withdrawn Claim Rejections - 35 USC § 101

2. The previous rejection of claims 1-18 under 35 U.S.C.101, regarding the claims being directed to non-statutory subject matter, is withdrawn in view of applicant's cancellation of the claim, and applicants' response at page 5 in the amendment filed December 8, 2006.

Withdrawn Claim Rejections - 35 USC § 112

3. The previous rejection of claims 1-16 and 19-20 under 35 U.S.C.112, first paragraph, scope of enablement, is withdrawn in view of applicant's cancellation of the claim, and applicant's response at page 6 in the amendment filed December 8, 2006.
4. The previous rejection of claims 1-16 and 19-20 under 35 U.S.C.112, first paragraph, written description, is withdrawn in view of applicant's cancellation of the claim, and applicant's response at pages 6-7 in the amendment filed December 8, 2006.
5. The previous rejection of claims 1-16 and 19-20 under 35 U.S.C.112, second paragraph, is withdrawn in view of in view of applicant's cancellation of the claim, and applicant's response at page 7 in the amendment filed December 8, 2006.

Withdrawn Claim Rejections - 35 USC § 103

6. The previous rejection of claims 1-2 under 35 U.S.C. 103(a) as being unpatentable over Maratos-Flier *et al.* (U. S. Patent 5,849,708), is withdrawn in view of applicant's cancellation of the claim, and applicant's response at page 7 in the amendment filed December 8, 2006.

Withdrawn Claim Rejections - Obviousness Type Double Patenting

7. The previous rejection of claims 1-3, 5-11, 14, 15 and 17-20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-30, 34-37 and 42-43 of co-pending Application No. 10/182,509, is withdrawn in view of applicant's cancellation of the claim in the amendment filed December 8, 2006.

New Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 29-33, 35-37 and 40-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 29-33, 35-37 and 40-41 are directed to a peptide having the structure of formula $Z^1-X^6\text{-cyclo}(X^7-X^8-X^9-X^{10}-X^{11}-X^{12}-X^{13}-X^{14}-X^{15}-X^{16})-X^{17}-Z^2$, where Z^1 , X^6 , X^7 , X^8 , X^9 , X^{10} , X^{11} , X^{12} , X^{13} , X^{14} , X^{15} , X^{16} , X^{17} and Z^2 are each defined in the claim, and where the substituent is optionally substituted with a detectable label; and a method of screening for a compound able to bind a MCH type 1 receptor (MCH-1R) by measuring the ability of the compound to inhibit

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binding of the peptide to the receptor. While the specification indicates a substituent on the peptide can be a detectable label, and detectable labels include luminescent, enzymatic and radioactive labels, and a preferred radiolabel is ^{125}I , and both the type of label and the position of the label can effect MCH activity (page 12, line 32 to page 13, line 2), the specification does not disclose a genus of variants for the peptides of formula having unspecified substituents, where the structure and location of the substituents are not defined. The substituent of a detectable label on the peptide does not provide sufficient description for the genus of variants for the peptides of formula having various substituents. Furthermore, there is no disclosure indicating the make/use of the peptides with various substituents, and their activity for MCH-1R. Without guidance on structure to function/activity of the peptide having various substituents, one skilled in the art would not know which peptides are functional. The lack of description on the structure to function/activity relationship of peptides with various substituents and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Response to Arguments

Applicants indicate claims 1-16, 19 and 20 were cancelled and replaced with new claims 29-41. The specification describes a core structure and variations to the structure that provides a framework for substituting a provided analog with a detectable label. The framework provides for activity at the MCH receptor. The detectable label is provided to produce a detectable signal. At the time the application was filed detectable labels were well known in the art. Examples of

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such labels noted by the application include luminescent, enzymatic, and a radiolabel (See page 12, line 32 to page 13, line 2 of the specification; pages 6- 7 of the response).

Applicants' response has been considered, regarding the detectable label, the arguments are persuasive, thus the substituent of a detectable label is not rejected. However, the claims also include a substituent which is not a detectable label and the structure of the substituent is not defined. The specification does not describe this undefined substituent on the peptide, thus the claims are rejected.

New Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 33, 38, 40 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 33 is indefinite because the claim recites X¹⁰ being arginine, which is not indicated in the independent claim, claim 29.

11. Claim 38 is indefinite because the claim recites the peptide being SEQ ID NO:34 containing citruline as X⁶, which is not indicated in the independent claim, claim 29.

12. Claims 40-41 are indefinite as to how the compound able to bind MCH-1R is identified, since the claim only recites the step of measuring the activity of the compound to inhibit binding of the peptide to MCH-1R, it does not indicate how the compound able to bind MCH-1R is identified. Claim 41 is included in the rejection because it is dependent on a rejected claim and does not correct the deficiency of the claim from which it depends.

Response to Arguments

Applicants indicate new claim 40 indicates measuring the ability of the compound to "inhibit" binding (page 7 of the response).

Applicants' response has been considered, however, the argument is not found persuasive because the claim does not indicate the step of identifying the compound able to bind MCH-1R (e.g., identifying the compound that inhibits binding as the compound able to bind MCH-1R).

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 29-32, 34-38, 40 and 41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-25, 28-30, 34, 36, 37 and 42-43 of co-pending Application No. 10/182,509 (based on the amended claims filed 12/14/06). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 29-32, 34-38, 40 and 41 in the instant application disclose a peptide having the structure of $Z^1-X^6\text{-cyclo}(X^7\text{-}X^8\text{-}X^9\text{-}X^{10}\text{-}X^{11}\text{-}X^{12}\text{-}X^{13}\text{-}X^{14}\text{-}X^{15}\text{-}X^{16})\text{-}X^{17}\text{-}Z^2$ with a substituent, where Z^1 , X^6 , X^7 , X^8 , X^9 , X^{10} , X^{11} , X^{12} , X^{13} , X^{14} , X^{15} , X^{16} , X^{17} and Z^2 are each defined in the claim, and where the substituent is optionally substituted with a detectable label;

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and a method of screening for a compound able to bind a MCH type 1 receptor (MCH-1R) by measuring the ability of the compound to inhibit binding of the peptide to the receptor. This is obvious variation in view of claims 22-25, 28-30, 34, 36, 37 and 42-43 in the co-pending application which disclose an optionally substituted peptide consisting of the structure of $Z^1-X^1-X^2-X^3-X^4-X^5-X^6\text{-cyclo}(X^7-X^8-X^9-X^{10}-X^{11}-X^{12}-X^{13}-X^{14}-X^{15}-X^{16})-X^{17}-Z^2$, where X^1, X^2, X^3, X^4, X^5 and X^{17} are not present, and $Z^1, X^6, X^7, X^8, X^9, X^{10}, X^{11}, X^{12}, X^{13}, X^{14}, X^{15}, X^{16}, X^{17}$ and Z^2 are each defined in the claim, or a labeled derivative of the peptide; and a method of screening for a compound able to bind a melanin concentrating hormone (MCH) receptor by measuring the ability of the compound to inhibit binding of the peptide to the receptor. Both the claims of the instant application and the claims of the co-pending application are directed to an optionally substituted peptide having the structure of $Z^1-X^6\text{-cyclo}(X^7-X^8-X^9-X^{10}-X^{11}-X^{12}-X^{13}-X^{14}-X^{15}-X^{16})-X^{17}-Z^2$, or a labeled derivative of the peptide; and a method of screening for a compound able to bind a MCH receptor by measuring the ability of the compound to inhibit binding of the peptide to the receptor, e.g., SEQ ID NO:48, 49, 51 and 52 of copending application of 10/182,509 are included in the peptides of claim 29 of the instant application. Thus, claims 29-32, 34-38, 40 and 41 in present application and claims 22-25, 28-30, 34, 36, 37 and 42-43 in the co-pending application are obvious variations of an optionally substituted peptide having the structure of $Z^1-X^6\text{-cyclo}(X^7-X^8-X^9-X^{10}-X^{11}-X^{12}-X^{13}-X^{14}-X^{15}-X^{16})-X^{17}-Z^2$, or a labeled derivative of the peptide; and a method of screening for a compound able to bind a MCH receptor by measuring the ability of the compound to inhibit binding of the peptide to the receptor.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants indicate claims 1-3, 5-11, 14, 15 and 17-20 were cancelled and prosecution of the present application and '509 is ongoing (page 8 of the response).

Applicants' response has been considered, since the scope of the new claims for the instant application are overlapped with the claims of co-pending application, 10/182509, the rejection is maintained.

Claim Objections

14. Claim 39 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

15. Claims 29-38 and 40-41 are rejected; and claim 39 is objected to.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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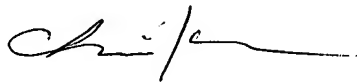
however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner



CHIH-MIN KAM
PRIMARY EXAMINER

CMK

February 23, 2007